



Michigan Certificate of Need

MAGNETIC RESONANCE IMAGING (MRI)
INFORMAL WORKGROUP

FEBRUARY 17, 2022

Recommended Changes

- ▶ Section 2 – add definition for “Hospital-Based Portable MRI”
- ▶ Section 3 – adjusted requirements to initiate MRI service
- ▶ Section 4 – adjusted requirements to replace an existing MRI unit
- ▶ Section 5 – added requirement for expansion of existing MRI service
- ▶ NEW Section 13 – Hospital-Based Portable MRI requirements
- ▶ Section 15 – modified number of required MRI adjusted procedures
- ▶ Section 15 – added project delivery requirements
- ▶ Section 16 – modified patient sedation values
- ▶ Section 19 – MRI adjusted procedure commitment exclusion for specific criteria

- ▶ WORKGROUP RECOMMENDATION
- ▶ DEPARTMENT RECOMMENDATION

Section 2

published in the Federal Register on August 14, 1995, or its replacement.

(p) "Health service area" or "HSA" means the geographic areas set forth in Section 2422.

(q) "HOSPITAL-BASED PORTABLE MRI" MEANS AN MRI UNIT THAT CAN BE TRANSPORTED INTO PATIENT CARE AREAS (E.G., DEDICATED NEUROSCIENCE UNIT, ICU, OPERATING ROOM) TO PROVIDE IMAGING OF THE BRAIN.

(r) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI services.

Section 3

Section 3. Requirements to initiate an MRI service

Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following requirements, as applicable:

- (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed service/unit.
- (2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):
 - (a) The applicant is currently an existing host site.
 - (b) The applicant has received in aggregate, one of the following:
 - (i) At least 6,000 MRI adjusted procedures.
 - (ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:
 - (A) Is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted.
 - (B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.
 - (iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:
 - (A) The proposed site is a hospital licensed under Part 215 of the Code.
 - (B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, OR 10,000 VISITS IF LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA, within the most recent 12-month period for which data, verifiable by the Department, is available.
- (c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.

Section 3

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

- (a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or
- (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and
- (c) The proposed host site has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(d) AN APPLICANT THAT OPERATES AN EXISTING FIXED MRI SERVICE AND IS PROPOSING TO INITIATE A MOBILE MRI HOST SITE AT THE SAME SITE SHALL NOT BE REQUIRED TO PROJECT AVAILABLE ADJUSTED PROCEDURES IF IT MEETS THE FOLLOWING REQUIREMENTS:

(i) EACH MOBILE MRI SERVICE(S) THAT PROPOSES TO PROVIDE MOBILE MRI SERVICES TO THE APPLICANT'S SITE CURRENTLY SERVES AND WILL CONTINUE TO SERVE AT LEAST TWO OTHER MOBILE HOST SITES.

Section 4

Section 4. Requirements to replace an existing MRI unit

Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) ~~an equipment change that involves a capital expenditure of \$750,000 or more in any consecutive 24-month period or (iii)~~ the renewal of a lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does not include the replacement of ~~components of the MRI system, including the magnet, THAT IS~~ under an existing service contract ~~or required maintenance to maintain the system to operate within manufacturer specifications~~. The term does not include an upgrade to an existing MRI unit or repair of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.

- (1) "Upgrade an existing MRI unit" means any equipment change that
- ~~(i) does not involve a change in, or replacement of, the entire MRI unit~~ **SYSTEM MAGNET**, does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit); ~~and~~
 - ~~(ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any consecutive 24-month period.~~

Section 4

(4) An applicant proposing to replace an existing mobile MRI host site to a new location shall demonstrate the following:

(a) The applicant currently operates the MRI mobile host site to be relocated.

(b) The MRI mobile host site to be relocated has been in operation as of the date an application is submitted to the Department.

(c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county.

(d) The relocation will not involve a change in the current central service coordinator unless the requirements of Section 3(5) are met.

(e) THE APPLICANT CONFIRMS THAT THE HOST SITE WAS NOT INITIATED UNDER SECTION 3(4)(d).

Section 5

Section 5. Requirements to expand an existing MRI service

Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

(1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:

(a) Each existing MRI unit on the network has performed at least an average of ~~9,000~~ 7,000 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed at least an average of ~~11,000~~ 9,000 MRI adjusted procedures per MRI unit.

(c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.

(d) THE APPLICANT OPERATES BOTH A FIXED MRI AND MOBILE MRI HOST SITE AT THE SAME SITE; AND

(i) THE SITE COLLECTIVELY PERFORMED AT LEAST AN AVERAGE OF 449,000 MRI ADJUSTED PROCEDURES PER EXISTING FIXED MRI UNIT WHEN ITS FIXED AND MOBILE HOST SITE MRI ADJUSTED PROCEDURES ARE COMBINED.

(ii) IT IS PROPOSING TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE PROPOSED FIXED MRI UNIT BECOMES OPERATIONAL.

SECTION 13. REQUIREMENTS FOR ALL APPLICANTS PROPOSING TO INITIATE, REPLACE, OR ACQUIRE AN FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT.

SEC. 13. AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE AN FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICANT IS LIMITED TO THE INITIATION, EXPANSION, REPLACEMENT, OR ACQUISITION OF NO MORE THAN TWO HOSPITAL-BASED PORTABLE MRI UNITS.

(2) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

(3) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS.

(4) THE APPLICANT HOSPITAL IS DESIGNATED AS A LEVEL I OR II TRAUMA FACILITY BY THE AMERICAN COLLEGE OF SURGEONS AND HAS BEEN CERTIFIED AS A COMPREHENSIVE STROKE CENTER BY THE JOINT COMMISSION, THE ACCREDITATION COMMISSION FOR HEALTH CARE, INC., OR DET NORSKE VERITAS OR HAS CARED FOR MORE THAN 500 ACUTE STROKE PATIENTS IN THE MOST RECENT 12-MONTH PERIOD IF LOCATED IN A METROPOLITAN COUNTY OR 300 ACUTE STROKE PATIENTS IN THE MOST RECENT 12-MONTH PERIOD IF LOCATED IN A RURAL OR MICROPOLITAN COUNTY.

(5) THE APPLICANT AGREES TO OPERATE THE FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 15 OF THESE STANDARDS.

(6) THE AUTHORIZED FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT WILL NOT BE SUBJECT TO MRI VOLUME REQUIREMENTS.

(7) THE APPLICANT MAY NOT UTILIZE MRI PROCEDURES PERFORMED ON AN FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

Section 15 (formerly 14)

(4) Compliance with the following monitoring and reporting requirements:

(a) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(i) ~~6,000~~ **5,000** MRI adjusted procedures per unit for fixed MRI services unless compliant with (A), ~~or (B) OR (C).~~

(A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

(C) 2,000 MRI ADJUSTED PROCEDURES PER UNIT PER YEAR FOR MRI SERVICES WITH ONE FIXED UNIT LOCATED OUTSIDE THE 20-MILE RADIUS FROM THE NEXT CLOSEST FIXED MRI SERVICE.

(ii) ~~5,500~~ **3,500** MRI adjusted procedures per unit for mobile MRI services.

(iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

(iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site.

(v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an IMRI unit approved pursuant to Section 9.

Section 15 (formerly 14)

(7) AN APPLICANT APPROVED UNDER SECTION 3(4)(d) SHALL AGREE THAT THE SERVICES PROVIDED BY THE MOBILE MRI SERVICE(S) ARE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS:

(a) EACH MOBILE MRI SERVICE(S) THAT PROVIDES MOBILE MRI SERVICES TO THE APPLICANT'S SITE ALSO SERVES AND WILL CONTINUE TO SERVE AT LEAST TWO OTHER MOBILE HOST SITES.

(78) AN APPLICANT APPROVED UNDER SECTION 13 SHALL BE IN COMPLIANCE WITH THE FOLLOWING:

(a) THE FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT CAN ONLY BE USED BY A QUALIFYING PROGRAM FOR BRAIN SCANNING OF PATIENTS BEING TREATED IN A DEDICATED NEUROSCIENCE UNIT, AN ADULT OR PEDIATRIC INTENSIVE CARE UNIT (ICU) AND/OR AN OPERATING ROOM.

(b) THE APPROVED APPLICANT MUST HAVE AN INSTITUTIONAL MRI SAFETY COMMITTEE.

(c) THE APPROVED APPLICANT MUST PROVIDE ANNUAL REPORTS TO THE DEPARTMENT BY APRIL 30TH OF EACH YEAR FOR THE PRECEDING CALENDAR YEAR, WHICH INCLUDE AT LEAST ALL OF THE FOLLOWING VISITS PERFORMED ON THE FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT:

(d) THE FOLLOWING PORTABLE MRI DATA MUST BE REPORTED TO THE DEPARTMENT:

(i) NUMBER OF ADULT VISITS (AGE ≥ 18)

(ii) NUMBER OF PEDIATRIC VISITS (AGE < 18)

(iii) NUMBER OF VISITS PERFORMED IN AN ICU

(iv) NUMBER OF VISITS PERFORMED IN A DEDICATED NEUROSCIENCE UNIT

(v) NUMBER OF VISITS PERFORMED IN AN OPERATING ROOM

Section 16 (formerly 15)

- Sec. 4516.** (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:
- (a) The base value for each MRI procedure is 1.0. For functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, the base value is 2.0.
 - (i) fMRI means brain activation studies.
 - (ii) MRI-guided interventions means any invasive procedure performed requiring MRI guidance performed in the MRI scanner.
 - (iii) Cardiac MRI Procedure means dedicated MRI performed of the heart done for the sole purpose of evaluation of cardiac function, physiology, or viability.
 - (b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.
 - (c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.
 - (d) For each MRI procedure performed on a sedated patient, ~~0.75 shall be added to the base value;~~
 - (i) 0.75 SHALL BE ADDED TO THE BASE VALUE FOR CONSCIOUS SEDATION; AND,
 - (ii) 1.50 SHALL BE ADDED TO THE BASE VALUE FOR GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS.
 - (e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base value.

Section 19 (formerly 18)

(3) SUBSECTION 19(2) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A MOBILE MRI HOST SITE UNDER SECTION 3(4)(d) IF THE MOBILE MRI HOST SITE WILL BE AT THE SAME SITE AS A FIXED MRI SERVICE AND THE HOST SITE WILL BE OWNED BY THE SAME APPLICANT ENTITY AS THE FIXED MRI SERVICE.